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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,002	08/31/2001	Roy Duncan	78973-1C/pw	9961

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,002	DUNCAN, ROY	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-28 and 41-77* is/are pending in the application.

4a) Of the above claim(s) *7-28,41-56 and 58-77* is/are withdrawn from consideration.

5)☒ Claim(s) *57* is/are allowed.

6)☒ Claim(s) *4* is/are rejected.

7)☒ Claim(s) *5 and 6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the directives of the response filed 5/12/05, claims 4-6 and 57 have been amended.

Claims 4-28, 41-77 remain pending.

Claims 4-6 and 57 are examined in this Office action; claims 7-28, 41-56, 58-77 remain withdrawn from consideration.

Applicants' arguments filed 5/12/05 have been considered and found persuasive in part. The rejection of claims 4-6 and 57 under 112, second paragraph is withdrawn. The rejection of claim 57 under 35 U.S.C. §103 is also withdrawn.

✧

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 4 is rejected under 35 U.S.C. §102 (a or b) as being anticipated by Subramanian (*Virus Genes* 15, 83, 1997) or Ernst (*Proc Natl Acad Sci* 82, 48, 1985).

Subramanian discloses a peptide obtained from a reovirus that has a molecular weight of 15.7 kD. Similarly, Ernst teaches a peptide obtained from a reovirus that has a molecular weight of 14 kD.

The recited properties are inherent.

In response, applicants have argued that they believe the prior art proteins each have a signal peptide, and an N-linked glycosylation signal. However, applicants have provided no evidence to support this assertion. Applicants have also argued that they believe that if the prior art proteins are injected into a mammal, the antibody response thereto will be greater than the proteins which applicants have tested. Again, there is no evidence to support this assertion. Applicants have also argued that they believe that there is no *alpha*-helical structure within the prior art proteins.

With regard to the claimed proteins, applicants have argued that if someone asserts something with regard to the physical properties of a claimed peptide, that assertion must be true, even if there is no evidence to support it. At the same time, applicants have argued that if someone other than an applicant makes an assertion about the physical properties of a protein, it must be untrue.

However, these two arguments are found to be contradictory. As it happens, the evidence in the reference as to the physical and biochemical properties of the proteins is at least as good as the evidence provided by applicants. In traversing, it is suggested that applicants are requested to point to the page and line number where evidence is presented to support the various assertions that have been made.

It remains the case that the recited properties are inherent.

✧

Claim 4 is rejected under 35 U.S.C. §102 (b) as being anticipated by Lin (*J Biol Chem* **269**, 1775, 1994).

Lin discloses a protein which is identified as bovine uroplakin II (UPII). This protein has a molecular weight of 15 kD and a transmembrane domain. It may be that the precursor of this protein contains a signal peptide, but the UPII itself does not.

Thus, the claim is anticipated.

✧

Claim 4 is rejected under 35 U.S.C. §102 (b) as being anticipated by Bandman (USP 5,955,283).

Bandman discloses (col 1, line 24+) a protein designated as phospholemman which contains 72 amino acids and which exhibits a molecular weight of 15 kD on gel electrophoresis. The protein also has a transmembrane domain.

Thus, the claim is anticipated.

✧

Claim 4 is rejected under 35 U.S.C. §102 (b) as being anticipated by Stinski (USP 5,180,813).

Stinski discloses (col 12, lines 25-55) a protein designated as "ORF3" which contains 148 amino acids and a molecular weight of 17 kD. The protein also has a transmembrane domain.

Thus, the claim is anticipated.

✧

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 4 is rejected under 35 U.S.C. §103 as being unpatentable over Papas (USP 5,674,705).

Papas discloses (col 2, line 50+ and col 6, line 48+) a protein which has a transmembrane domain and a molecular weight of 15.88 kD.

The reference does not disclose that the average molecular weight of the amino acids contained therein is greater than 105.9 g/mol (which would be required by instant claim 4 for a molecular weight of 15.88 kD). However, the protein chemist of ordinary skill would not expect that a naturally occurring, virally expressed protein would be limited to glycine, alanine and proline.

Thus, the claim is rendered obvious.

✧

Claim 4 is rejected under 35 U.S.C. §103 as being unpatentable over Kawasaki (USP 5,470,569).

Kawasaki discloses (col 14, line 9+) a protein that has a molecular weight of 14-15 kD, and a transmembrane domain.

Kawasaki does not disclose that the average molecular weight of the amino acids contained therein is greater than 100 g/mol (which would be required by instant claim 4 for a molecular weight of 15 kD). However, the protein chemist of ordinary skill would not expect that a naturally occurring mammalian protein would be limited to glycine, alanine and proline.

Thus, the claim is rendered obvious.

✧

Claim 4 is rejected under 35 U.S.C. §103 as being unpatentable over Wilson (USP 6,153,188).

Wilson discloses (col 15, line 25+) a protein that has a molecular weight of 14 kD, and a transmembrane domain. Wilson does not disclose that the average molecular weight of the amino acids contained therein is greater than 93.33 g/mol (which would be required by instant claim 4 for a molecular weight of 14 kD). However, the protein chemist of ordinary skill would not expect that a naturally occurring mammalian protein would be limited to glycine and alanine.

Thus, the claim is rendered obvious.

✦

Claim 4 is rejected under 35 U.S.C. §103 as being unpatentable over Stein (USP 5,545,626).

Stein discloses (col 3, line 57+) a protein that has a molecular weight of 15 kD, and a transmembrane domain.

Stein does not disclose that the average molecular weight of the amino acids contained therein is greater than 100 g/mol (which would be required by instant claim 4 for a molecular weight of 15 kD). However, the protein chemist of ordinary skill would not expect that a naturally occurring mammalian protein would be limited to glycine, alanine and proline.

Thus, the claim is rendered obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600